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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,603	04/16/2004	James D. Thacker	8109.005.US	8050

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,603	THACKER ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *15,16,18,19,21-24 and 28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,17,20,25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-30 are pending.

2. Applicant's election with traverse of Group I, claims 1-14, 17, 20 and 25-27, drawn to an isolated peptide and the elected species of SEQ ID No:3 are acknowledged.

Upon further consideration, the requirement for species election has been withdrawn.

Applicants traversed the restriction requirement based on that there is no serious search burden imposed. This is not found persuasive because the pending claims of each group from the original restriction are patentably distinct methods as referred in this restriction requirement. It is undue burden to search more than one invention. A prior art reads on a method for treating a disease with a peptide differs from a prior art reads on method for isolating the peptide. The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 15-16, 18, 19, 21-24 and 28-30 are withdrawn from further consideration by the examiner 37CFR 1.142(b) as being drawn to a nonelected invention.

Claims 1-14, 17, 20 and 25-27, drawn to an isolated peptide are under consideration in the instant application.

3. Sequence compliance: The instant application appears to be in sequence compliance for patent applications containing amino acid sequence disclosures.

4. Applicant's claim for domestic priority under 35. U.S.C. 119(e) is acknowledged.

5. Applicant is invited to file IDS for consideration.

6. Applicant is required to update US priority in the first line of the specification.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 17 and 20 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 20 are indefinite in that it is depended on non-elected claims and should be written as independent claims.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out this invention.

10. Claims 1-14, 17, 20 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated peptide consisting a nonapeptide as in SEQ ID NOs: 1-3 and 5 wherein the nonapeptide consists of up to three fatty acids are selected from the group consisting of stearic acid, arachidic acid and arachadonic acid, does not reasonably provide enablement for any isolated peptides having an amino acid terminus and a carboxy terminus comprising the SEQ ID NO:1-3 or 5, any isolated peptides comprising an nonapeptide or any isolated peptides comprising the SEQ ID NOs: 1-3 or 5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use of the invention commensurate in scope with these claims.

The specification disclosure does not enable one skilled in the art to practice the invention without any undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and

the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

The term "comprising" or "having" in claim 1 is open-ended. It expands the amino acid sequence of SEQ ID NO:1-3 and 5 to include additional non-disclosed amino acids. The SEQ ID NO:3 and SEQ ID NOs: 1, 2 and 5 are oligopeptides consist of 6 and 9 amino acids, respectively. The specification does not provide sufficient guidance as to which amino acid sequence can be added to the oligopeptides which retain a distinct functional property such as immunostimulating property of the SEQ ID NO:1-3 and 5.

The art recognizes that even minor structural differences among structurally related compounds or compositions can result in substantially different or deleterious biological activities. Ngo *et al* teach that the amino acid positions within the polypeptide/protein that can tolerate change such as conservative substitution or no substitution, addition or deletion which are critical to maintain the protein's structure will require guidance (see Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495 in particular).

In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Since the amino acid sequence of a polypeptide determined its structural property, predictability of which amino acid fragment can retain the functional capabilities of the TGF-beta comprising polypeptide requires knowledge of, and guidance with regard to, which segments in the polypeptide's sequence contribute to its function.

Therefore, there is insufficient direction as to how to make any isolated peptide having an amino acid terminus and a carboxy terminus comprising the SEQ ID NO:3 any isolated peptides having an amino acid terminus and a carboxy terminus comprising the SEQ ID NO:1-3 or 5, any isolated peptides comprising an nonapeptide or any isolated peptides comprising the SEQ ID NOs: 1-3 or 5 which can be used as to whether such a desired effect can be achieved or predicted, as encompassed by the claims. In view of the quantity of experimentation necessary, the limited working example, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

11. Claims 1-14, 17, 20 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of an isolated peptide consisting a nonapeptide as in SEQ ID NOs:1-3 and 5 wherein the nonapeptide consists of up to three fatty acids are selected from the group consisting of stearic acid, arachidic acid and arachadonic acid; however, applicant is not in possession of any isolated peptides having an amino acid terminus and a carboxy terminus comprising the SEQ ID NO:1-3 or 5, any isolated peptides comprising an nonapeptide or any isolated peptides comprising the SEQ ID NOs: 1-3 or 5.

Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1, 7, 17, 20 and 25-27 are rejected under 35 U.S.C. 102(a)(e) as being anticipated by U.S. Pub. No. 2002/0165123A1.

The '123 publication teaches isolated peptides comprising the claimed SEQ ID NO:3 ([0045], SEQ ID NOs:1-4, 6-13, in particular). The '123 publication further teaches a therapeutic composition comprising a pharmaceutically acceptable carrier such as water, oil or glycerols (claims 1-6, col. 8-9, in particular).

The patentability of a product does not depend on its method of production. Having an amino acid terminus and a carboxy terminus is inherent property of polypeptide. As therapeutic compositions are free of any agents promoting a pyrogenic response, it is inherent property of the therapeutic composition comprising SEQ ID NO:3 and a pharmaceutically acceptable carrier. Therefore, the reference teaching anticipates the claimed invention.

14. Claims 1, 7, 17, 20 and 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. U.S. Pat. No. 6,875,738.

The '738 patent teaches the isolated peptides comprising the claimed SEQ ID NO:3 (col. 4, lines 44-67, SEQ ID NOs:1-4, 6-7, in particular). The '738 patent further teaches a therapeutic composition comprising a pharmaceutically acceptable carrier such as water, oil or glycerols (col. 8-9, in particular).

The patentability of a product does not depend on its method of production. Having an amino acid terminus and a carboxy terminus is inherent property of polypeptide. As therapeutic compositions are free of any agents promoting a pyrogenic response, it is inherent property of the therapeutic composition comprising SEQ ID NO:3 and a pharmaceutically acceptable carrier. Therefore, the reference teaching anticipates the claimed invention.

15. Claims 1, 7, 17, 20 and 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. U.S. Pat. No. 6,946,445.

The '445 patent teaches the isolated peptide comprising the claimed SEQ ID NO:3 (col. 5, lines 36-65, SEQ ID NOs:1-4, 6-7, in particular). The '445 patent further teaches a therapeutic composition comprising a pharmaceutically acceptable carrier such as water, oil or glycerols (claims 1-15, col. 8-9, in particular).

The patentability of a product does not depend on its method of production. Having an amino acid terminus and a carboxy terminus is inherent property of polypeptide. As therapeutic compositions are free of any agents promoting a pyrogenic response, it is inherent property of the therapeutic composition comprising SEQ ID NO:3 and a pharmaceutically acceptable carrier. Therefore, the reference teaching anticipates the claimed invention.

16. No claims are allowable.
The isolated polypeptide consisting of the SEQ ID NOs:1-3 or 5 is free of art.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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